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TITLE 9--ANIMALS AND ANIMAL PRODUCTS

CHAPTER I--ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

PART 116--RECORDS AND REPORTS

Sec. 116.1 Applicability and general considerations.

(a) Each licensee, permittee, and foreign manufacturer of biological products imported into the United States shall maintain, at the licensed or foreign establishment in which the products are prepared, detailed records of information necessary to give a complete accounting of all the activities within each establishment. Such records shall include, but shall not be limited to, the items enumerated in this part.

(1) Records shall be made concurrently with the performance of successive steps in the development and preparation of biological products, including new products under development. Such records shall include the date and where critical, the time that each essential step was taken, the identity and quantity of ingredients added or removed at each step, and any gain or loss of product from the beginning to the end of product preparation.

(2) Records shall be legible and indelible; shall be as detailed as necessary for a clear understanding of each step by one experienced in the preparation of biological products; and shall be verified by initials or signature of the person immediately responsible for the action taken.

(3) Records (other than disposition records) required by this part shall be completed by the licensee or the foreign manufacturer, as the case may be, before any portion of a serial of any product shall be marketed in the United States or exported.

(b) If, at any time, there are indications that raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product, the licensee, permittee, or foreign manufacturer must immediately notify the Animal and Plant Health Inspection Service concerning the circumstances and the action taken, if any. Notification may be made by mail to Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA 50010-8197; by electronic mail to cvb@usda.gov; by fax to (515)

232-7120; or by telephone to (515) 232-5785.

(c) When authorized by the Administrator, the licensee, permittee, or foreign manufacturer may maintain and retain records required under this part at an alternative location. Such authorization shall be confirmed by the filing of an addendum to the plot plan legend. The addendum shall list the location of the records and the condition of their storage and shall permit the inspection of the records by APHIS inspectors, or foreign inspectors acting on behalf of APHIS.

(Approved by the Office of Management and Budget under control number 0579-0013)

[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 61 FR 52874, Oct. 9, 1996; 64 FR 43045, Aug. 9, 1999; 66 FR 21064, Apr. 27, 2001]

Sec. 116.2 Inventory and disposition records.

(a) Records shall show the quantity and location of each biological product being prepared, in storage, and in distribution channels.

(b) Detailed disposition records, in a form satisfactory to the Administrator, shall be maintained by each licensee, each distributor, and each permittee showing the sale, shipment, or other disposition made of the biological products handled by such person.

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Sec. 116.3 Label records.

(a) Each licensee and permittee shall maintain a list of all approved labels currently being used. Each label shall be identified as to:

(1) Name and product code number as it appears on the product license or permit for the product;

(2) Where applicable, the size of the package (doses, ml, cc, or units) on which the label shall be used;

(3) Label number and date assigned; and

(4) Name of licensee or subsidiary appearing on the label as the producer.

(b) All labels printed shall be accounted for and an inventory

maintained.

Records shall include the disposition of such labels including those not used in labeling a product.

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[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 61 FR 52874, Oct. 9, 1996; 66 FR 21064, Apr. 27, 2001]

Sec. 116.4 Sterilization and pasteurization records.

Records shall be made by means of automatic recording devices or an equivalent accurate and reliable system. Such records shall be identified with the ingredients, equipment, or biological product subjected to sterilization or pasteurization.

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[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 61 FR 52874, Oct. 9, 1996; 66 FR 21064, Apr. 27, 2001]

Sec. 116.5 Reports.

(a) When required by the Administrator, reports containing accurate and complete information concerning biological products, including but not limited to, product development and preparation, and market suspensions and recalls, shall be prepared and submitted to the Animal and Plant Health Inspection Service by the licensee, permittee, or foreign manufacturer (whose products are being imported or offered for importation). Unless otherwise authorized by the Administrator, records necessary to make such reports shall be maintained in each establishment.

(b) If, at any time, there are indications that raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product, the licensee, permittee, or foreign manufacturer must immediately notify the Animal and Plant Health Inspection Service concerning the circumstances and the action taken, if any. Notification may be made by mail to Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA 50010-8197; by electronic mail to cvb@usda.gov; by fax to (515) 232-7120; or by telephone to (515) 232-5785.

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[61 FR 52874, Oct. 9, 1996, as amended at 64 FR 43045, Aug. 9, 1999]

Sec. 116.6 Animal records.

Complete records shall be kept for all animals at a licensed establishment. Results of tests performed, antigens or treatment administered, maintenance and production records, disposition records, necropsy records, if any, and all other pertinent records shall be included.

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Sec. 116.7 Test records.

Detailed records of all tests conducted on each serial and each subserial shall be maintained by the licensee. Summaries of such tests shall be prepared from such records and submitted to the Animal and Plant Health Inspection Service using APHIS Form 2008 or an acceptable equivalent form prior to release of the serial or subserial. Blank forms for such summaries shall be available from Animal and Plant Health Inspection Service upon request.

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[39 FR 16872, May 10, 1974, as amended at 48 FR 57473, Dec. 30, 1983; 56 FR 66784, Dec. 26, 1991; 61 FR 52874, Oct. 9, 1996]

Sec. 116.8 Completion and retention of records.

All records (other than disposition records) required by this part shall be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. All records shall be retained at the licensed or foreign establishment or permittee's place of business for a period of two years after the expiration date of a product, or for such longer period as may be required by the Administrator.

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